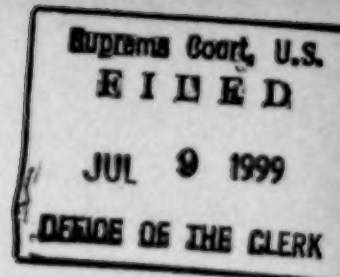


(24)

No. 98-1152

IN THE



**Supreme Court of the United States**

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FOOD AND DRUG ADMINISTRATION,

*Petitioner,*

v.

BROWN & WILLIAMSON TOBACCO CORP., ET AL.,

*Respondents.*

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On Writ of Certiorari to the  
United States Court of Appeals  
for the Fourth Circuit

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**BRIEF OF  
AMERICAN COLLEGE OF CHEST PHYSICIANS  
AS AMICUS CURIAE IN SUPPORT OF PETITIONER**

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**Raymond D. Cotton\***  
**Aliza A. Danoff**  
MINTZ LEVIN COHN FERRIS  
GLOVSKY & POPEO, P.C.  
701 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
(202) 434-7300

*Attorneys for American College  
of Chest Physicians*

\* Counsel of Record

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B.S. Lynch, R.S. Bonnie, eds. <i>Growing Up Tobacco Free: Preventing Nicotine Addiction In Children And Youths</i> . National Academy Press, 1994 .....	3
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C.A. Dukes, 1975 Marketing Plans Presentation to RJRI Board of Directors (September 30, 1974). Trial Exhibit #12493 .....	18
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D. Kessler, <i>Nicotine Addiction in Young People</i> , 333 New Eng. J. Med., 186-189 (1995) .....	17
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Denissenko et. al., Science, October 18, 1996 .....	20

<i>Domestic Operating Goals</i> (November 26, 1974). Trial Exhibit #12377 .....	18
Finette et al., Nature Medicine, October 1998 .....	19
G. Bible, Minnesota Tobacco Trial Transcript at 6097 (March 8, 1998) .....	18
Gold et al., New Eng. J. Med., September 26, 1996 ..	19
J.D. Blackhurst, <i>Further Work on "Extractable" Nicotine</i> . Report issued by I.W. Hughes (September 30, 1966). Trial Exhibit #17825 .....	11
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Letter to A.Y. Yeaman (July 4, 1963). Trial Exhibit #13905 .....	6
MacKensie et al., New Eng. J. Med., April 7, 1994 ..	18
<i>Marlboro</i> (March 29, 1979). Trial Exhibit #11808 .....	18
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Memorandum to Dr. L.C.F. Blackman and Mr. A.M. Heath, <i>Proceedings Of The Smoking Behavior- Marketing Conference</i> , July 9-12, 1984, session I (July 30, 1984). Trial Exhibit #13430 .....	13
N.L. Benowitz, J.E. Henningfield, <i>Establishing A Nicotine Threshold for Addiction</i> , 331 New Eng. J. Med., 123-125 (1994) .....	9

P. Hiltz, <i>Tobacco Company Was Silent on Hazards</i> , New York Times, 1994 .....	16
R.A. Crellin, <i>Brainstorming II: What Three Radical Changes Might, Through the Agency of R&amp;D, Take Place in this Industry by the End of the Century?</i> (April 11, 1980). Trial Exhibit #11361 .....	16
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R.K. Williams, <i>Development Of A Cigarette With Increased Smoke pH</i> (December 16, 1971). Trial Exhibit #11903 .....	11
R.R. Johnson, Ammonia Technology Conference Minutes, Louisville, KY, May 18-19, 1989 (June 12, 1989). Trial Exhibit #13069 .....	12, 13
S.A. Glantz, D.E. Barnes, L. Bero, P. Hanauer, J. Slade, <i>Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson documents</i> , 274 JAMA 219-224 (1995); P. Hanauer, J. Slade, D.E. Barnes, L. Bero, S.A. Glantz, <i>Lawyer Control of Internal Scientific Research to Protect Against Products Liability Lawsuits: The Brown and Williamson documents</i> , 274 JAMA 234-240 (1995); L. Bero, D.E. Barnes, P. Hanauer, J. Slade, S.A. Glantz, <i>Lawyer Control of the Tobacco Industry's External Research Program: The Brown and Williamson documents</i> , 274 JAMA 241-247 (1995) .	17
<i>The Effects of Cigarette Smoke "pH" on Nicotine Delivery and Subjective Evaluations</i> (June 24, 1994). Trial Exhibit #11752 .....	14



The Nowland Organization, Inc., Management Report: SHF Cigarette Marketplace Opportunities Search and Situation Analysis, Volume II (December 1976). Trial Exhibit #17994 .....	10
The Roper Organization Inc., <i>A Study of Smoking Habits Among Young Smokers</i> (July 1974). Trial Exhibit #10497 .....	18
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#### OTHER

Trial Exhibits from *State of Minnesota et al. v. Philip Morris Inc., et al.*, 551 N.W.2d 490 (1996) can be viewed on the Internet at <http://www.mnbluecrosstobacco.com>.

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for the Fourth Circuit

### BRIEF OF AMERICAN COLLEGE OF CHEST PHYSICIANS AS AMICUS CURIAE IN SUPPORT OF PETITIONER

The American College of Chest Physicians, pursuant to Supreme Court Rule 37, submits this brief *amicus curiae* in support of Petitioner, the Food and Drug Administration ("FDA"), seeking reversal of the United States Court of Appeals for the Fourth Circuit's ruling that the Food, Drug, and Cosmetic Act ("FDCA") does not authorize the FDA to regulate the sale and promotion of tobacco products. The American College of Chest Physicians has received the consent of all parties to file this brief as *amicus curiae*, and letters of consent have been filed concurrently with this brief.<sup>1</sup>

<sup>1</sup> Pursuant to Rule 37.6 of this Court, the Amicus states that no party had any role in writing this brief and that no one other than the Amicus or their counsel made a monetary contribution to its preparation or submission.

### INTEREST OF THE AMICUS CURIAE<sup>2</sup>

As the first hand observers of hundreds of thousands of deaths each year caused by tobacco usage, the members of the American College of Chest Physicians urge this Court to recognize that unless a national approach is undertaken to regulate the sale and promotion of tobacco products, our children will continue to become morbidity statistics with one third of those using tobacco products dying prematurely. It is for this reason that the American College of Chest Physicians supports the FDA's rule restricting the sale and promotion of tobacco products to children, 61 Fed. Reg. 44,396 (1996), and seeks reversal of the Fourth Circuit's ruling. In their briefs, Petitioner and the Amici analyze the legal aspects of FDA jurisdiction. It is not our purpose to repeat those arguments. We believe, however, that a decision as to whether tobacco products fall within the jurisdiction of the FDA under the FDCA is intimately intertwined with the medical evidence related to the health hazards associated with smoking and the addictive nature of nicotine in tobacco leaves and tobacco smoke. The overwhelming medical, scientific, and internal tobacco industry evidence demonstrates that our children are anything but immune to these health hazards and will more than likely fall prey to the addictive nature of nicotine unless something is done on a national level to shield them from nicotine addiction and the resulting diseases and death associated with the use of tobacco products.

<sup>2</sup> Counsel to the American College of Chest Physicians consulted extensively with Richard D. Hurt, M.D., FACP, Professor of Medicine, Mayo Medical School, Director, Mayo Nicotine Dependence Center; D. Robert McCaffree, M.D., FCCP, Chief of Staff, University of Oklahoma, Health Science Center; Edward C. Rosenow, III, M.D., Master FCCP, MACP, Emeritus Professor, Mayo Medical School; Diane E. Stover, M.D., FCCP, Div. Head-Gen Med., Sloan Kettering Cancer Center; and John E. Studdard, M.D., FCCP, Jackson Pulmonary Associates. Additionally, Alvin Lever, Executive Vice President and Chief Executive Officer of the American College of Chest Physicians, and Lynne G. Marcus, Vice President, Membership and Public Affairs of the American College of Chest Physicians, contributed significantly to the writing of this brief.

### Identity of the Amicus

The American College of Chest Physicians ("ACCP"), founded in 1935 as a medical and scientific society, is dedicated to providing postgraduate medical education for physicians, surgeons and allied health professionals involved in the diagnosis and treatment of chest diseases, including those long-term debilitating cardiopulmonary diseases induced by or exacerbated by inhalation of tobacco smoke, e.g., lung cancer, emphysema, coronary artery disease, arteriosclerosis obliterans affecting the lower extremities, bronchitis and asthma. Specialties represented by members are pulmonary disease, cardiology, cardiothoracic surgery, critical care medicine, anesthesiology, infectious disease, allergy, and related specialties. Approximately 13,000 members practice medicine and surgery in the United States and Canada and another 1,800 members practice in ninety countries worldwide. Members of the ACCP are professionally involved with the adverse effects of smoking, treating those patients who suffer from heart and lung disease on a daily basis. Every Fellow of the ACCP during the last ten years has pledged to promote the cessation of smoking among his or her patients (see Appendix A). This pledge reflects the ACCP's sincere goal to reduce or prevent cardiopulmonary disease.

As physicians, we confront on a daily basis debilitating disease and death that result from inhalation of tobacco smoke. In this century more people have died of the adverse effects of tobacco than in all the wars combined. It kills more people than AIDS, car accidents, alcohol, homicides, illegal drugs, suicides and fires combined.<sup>3</sup> With over 400,000 deaths annually attributable to the effects of smoking, smoking diseases, such as lung cancer, emphysema, and coronary artery disease, and other cardiopulmonary diseases have become a major socioeconomic problem of transcending importance. Treatment of these diseases will continue to drain over \$800 billion from the Medicare

<sup>3</sup> B.S. Lynch, R.S. Bonnie, eds. *Growing Up Tobacco Free: Preventing Nicotine Addiction In Children And Youths*. National Academy Press, 1994, at 3.



Trust Fund. The Veterans Administration spends over one-half billion dollars annually on inpatient care of smoking-related diseases.<sup>4</sup> There are over 40 diseases/conditions that are caused by or aggravated by the use of tobacco. Thus, it is by far the most preventable cause of illness and of premature death in this country. With the exception of dying suddenly from a heart attack or stroke, the vast majority of these people die a chronic, lingering, long-suffering and expensive death.

The concern of the Amicus is magnified by the fact that tobacco smoke contains a powerful addictive drug, nicotine. Because of this highly addictive substance, many individuals find it exceptionally difficult, if not impossible, to stop smoking even when they want to, as do at least 50% of teenagers, or when their physicians advise them of the dangers to their health.

Medical science has made giant strides in eliminating some diseases that have afflicted populations in the United States and throughout the world. The ACCP continues to seek new and improved treatments and procedures (including surgery) to ameliorate the effects of diseases resulting from the direct and indirect inhalation of tobacco smoke. But, unlike other diseases which medical science has conquered or substantially reduced, elimination or control of smoking diseases is thwarted by nicotine addiction that renders normal precautionary advice and warnings ineffective.

The ACCP respectfully urges this Court to consider the medical, historical context and, in particular, the powerful addictive nature of tobacco smoke in its deliberation over the nationally important issues presented by this case.

#### SUMMARY OF THE ARGUMENT

The tobacco industry has known but has surreptitiously hidden evidence for decades that nicotine, the addictive agent in tobacco, is a drug which causes adverse health effects, often

<sup>4</sup> 1992 Annual Report of the Secretary of Veterans Affairs, U.S. Dept. of Veterans Affairs (March 1993).

times leading to chronic illness and death. Overwhelming medical evidence indicates that the younger one starts smoking, the more debilitating are the health effects associated with tobacco usage. Internal industry research has revealed that the tobacco industry capitalized on children's inability to exercise mature judgments and thus their inability to make appropriate choices. Recognizing this, the industry purposefully directed its sales and promotion efforts to the teenage population of this country.

The totality of medical evidence compels the social and legal conclusion that something needs to be done on a national scale to protect our children against the devastating effects of nicotine and tobacco usage. Unless the FDA is found to have the legal authority to regulate the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, this population will continue to be targeted by the industry thereby accelerating the likelihood that they will be plagued with the chronic illnesses associated with nicotine addiction and tobacco usage. The preponderance of medical evidence mandates that nicotine be treated as a drug and accordingly, that the FDA be found to have the legal authority to regulate tobacco products.

#### ARGUMENT

**THE LEGAL AUTHORITY OF THE FDA TO REGULATE THE SALE AND PROMOTION OF TOBACCO PRODUCTS TO CHILDREN IS ESSENTIAL, AS THIS VULNERABLE POPULATION IS IN NO POSITION TO PROTECT ITSELF AGAINST THE ADDICTIVE NATURE OF NICOTINE, A DEBILITATING DRUG WHICH IS CAUSALLY RELATED TO CHRONIC DISEASE AND DEATH. ACCORDINGLY, THE FOURTH CIRCUIT'S DECISION SHOULD BE REVERSED.**

##### A. What The Industry Failed To Tell Us

While the 1988 Surgeon General's Report entitled "Nicotine Addiction" is considered by most experts as the first comprehensive scientific document on the issue, it is now known that decades before, the tobacco industry identified nicotine as

the addictive agent in cigarette smoke.<sup>5</sup> In fact, if the Advisory Committee to the Surgeon General in 1964 had available to it internal tobacco company research documents, it very well could have come to the conclusion at that time that nicotine was addictive. However, information contained in tobacco company files was not turned over as indicated by a July 4, 1963, letter from British American Tobacco to Addison Yeaman, lead counsel for Brown & Williamson ("B&W"), expressing the opinion of British American Tobacco senior scientist Sir Charles Ellis: "TRC consultant scientists advise it is too early to submit Battelle reports to Surgeon General's Committee . . . Charles' view is that as the situation has now developed, it would be wiser for B&W not to take the initiative in submitting anything to the Surgeon General's Committee but rather wait and hope that the Committee will ask individual manufacturers for further details of their research work . . .".<sup>6</sup>

Most of this information has since become public as a result of documents released during the Minnesota tobacco trial of 1998. For example, in 1962, Sir Charles Ellis, of British American Tobacco, stated, "... we now possess a knowledge of the effects of nicotine far more extensive than exists in published scientific literature . . . We believe that we have found possible reasons for addiction in two other phenomena that accompany steady absorption of nicotine. Experiments have so far only been carried out with rats, but with these it is found that certain rats become tolerant to repeated doses and after a while show the usual nicotine reactions but only on a very diminished scale. . . . Supposing the tranquilizing action of nicotine can be tracked down in this way, then these reactions will be compared in the case of rats who have never had nicotine, or alternatively have become addicted to it. Subsequent similar measurements

<sup>5</sup> R.D. Hurt, C.R. Robertson, *Prying Open the Door to the Tobacco Industry's Secrets About Nicotine: The Minnesota Tobacco Trial*, 280 JAMA 1173-1181 (1998).

<sup>6</sup> Letter to A.Y. Yeaman (July 4, 1963). Trial Exhibit #13905.

will be made on human nonsmokers and on addicted smokers."<sup>7</sup> In a 1978 B&W memo from H. D. Steele to M. J. McCue, Steele stated, "Very few consumers are aware of the effects of nicotine, i.e., its addictive nature and that nicotine is a poison."<sup>8</sup> Other memos were much more blunt. A 1983 B&W memo stated, "Nicotine is the addicting agent in cigarettes."<sup>9</sup>

#### B. How Nicotine Works To Addict

Pharmacologically, nicotine enters the blood stream rapidly from the lungs and is distributed to the brain, where it affects the central nervous system. More particularly, nicotine acts on specific receptors in specific areas of the brain (the mesolimbic system) which produce the pleasure and reward phenomenon which is a reinforcer of nicotine addiction. These effects are mediated by the neurotransmitter dopamine which is released in large quantities by nicotine. The Surgeon General's Report of 1988 stated, "The pharmacologic and behavioral process that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." The following criteria, used to determine substance dependence, were developed by a task force of experts and published by the American Psychiatric Association as the Diagnostic and Statistical Manual of Mental Disorders—Fourth Edition ("DSM-IV"). Substance Dependence: A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

- 1) tolerance
- 2) withdrawal

<sup>7</sup> C. Ellis, Proposal for Further Research Contracts with Battelle: *The Effects of Smoking* (February 13, 1962). Trial Exhibit #11938 from *State of Minnesota et al. v. Philip Morris Inc., et al.*, 551 N.W2d 490 (1996). Hereinafter, all references to Trial Exhibits refer to this case. These Trial Exhibits can be viewed on the Internet at <<http://www.mnbluecrosstobacco.com>>.

<sup>8</sup> Memorandum from H.D. Steele to M.J. McCue, *Future Consumer Reaction to Nicotine* (August 24, 1978) (emphasis supplied). Trial Exhibit #13677.

<sup>9</sup> Memorandum from A.J. Mellman to R.A. Blott, *Project Recommendations* (March 25, 1983). Trial Exhibit #13344.



- 3) the substance is often taken in larger amounts or over a longer period than was intended
- 4) persistent desire or unsuccessful efforts to cut down or control substance use
- 5) a great deal of time is spent in activities necessary to obtain the substance
- 6) important social, occupational, or recreational activities are given up or reduced because of substance use
- 7) the substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance

DSM-IV diagnostic criteria for nicotine withdrawal are:

Abrupt cessation of nicotine use, or reduction in the amount of nicotine used, followed within 24 hours by four (or more) of the following signs:

- 1) insomnia
- 2) irritability, frustration, or anger
- 3) anxiety
- 4) difficulty concentrating
- 5) restlessness
- 6) decreased heart rate
- 7) increased appetite or weight gain

Though not included in the diagnostic criteria, craving is an important element in nicotine withdrawal and may account for the difficulty that individuals have in giving up nicotine-containing products.

#### C. Nicotine the Addicting Drug and the Threshold Dose of Nicotine

For cigarettes, as with all drug delivery devices, it is critical to ensure that the drug (i.e. nicotine for cigarettes) is delivered to the recipient within a dose range window, the upper bound dictated by toxicity and the lower bound defined by the minimal dose required to achieve the desired pharmacological effect: in

this case nicotine addiction. Recent proposals from the scientific community have called for consideration of reducing the absolute level of nicotine in cigarettes to a point where children who experiment with cigarettes would not be able to become dependent.<sup>10</sup> The industry also focused on this "threshold dose" but from the opposite perspective, i.e., not to avert addiction but to maintain it. A 1980 Lorillard document summarized the goals of an internal task force, one of which was to, "Determine the minimum level of nicotine that will allow continued smoking. We hypothesize that below some very low nicotine level, diminished physiological satisfaction cannot be compensated for by psychological satisfaction. At this point, smokers will quit or return to higher T&N (*tar and nicotine*) brands."<sup>11</sup>

For decades, industry scientists, executives and lawyers have known full well that nicotine is addicting and that they are in the business of developing, manufacturing and selling a drug delivery device—the cigarette. "No one has ever become a cigarette smoker by smoking cigarettes without nicotine."<sup>12</sup>

#### D. The Deception of the Century: "Low Tar, Low Nicotine Cigarettes"

A December 1976 Lorillard document outlined the impression most people had (and still have) about low tar and nicotine cigarettes: "People believe that cigarettes low in tar and nicotine have different 'tobacco' ingredients and different kinds of filters than other cigarettes—the tobacco is milder or a special mild blend, perhaps treated to remove tar and nicotine, perhaps mixed with additives or fillers, perhaps cured differently—or maybe just more loosely packed . . . Those who smoke low tar

<sup>10</sup> N.L. Benowitz, J.E. Henningfield, *Establishing A Nicotine Threshold for Addiction*, 331 New Eng. J. Med., 123-125 (1994).

<sup>11</sup> Memorandum from R.E. Smith to J.R. Ave, J.G. Flinn and A.W. Spears (February 13, 1980). Trial Exhibit #10170.

<sup>12</sup> W.L. Dunn, Jr., *Motives and Incentives in Cigarette Smoking* (1972). Trial Exhibit #18089.

and nicotine cigarettes generally do so because they believe such cigarettes are 'better for you'."<sup>13</sup>

Industry scientists were well aware that smokers compensated by taking more puffs and/or larger puffs when smoking low tar/low nicotine products. Thus, the amount of nicotine ingested was similar to that from full flavor cigarettes. A 1978 British Tobacco Company document by D. E. Creighton defined compensation to mean "subconscious changes made to the smoking pattern by a smoker in an attempt, which may or may not be successful, to equalize the deliveries of products which have different deliveries when smoked by machine under standard conditions."<sup>14</sup> He went on to say: "[T]here is now sufficient evidence to challenge the advice to change to a lower delivery brand, at least in the short-term. In general, a majority of habitual smokers compensate for changed delivery, if they change to a lower delivery brand than their usual brand. If they choose a lower delivery brand which has a higher tar to nicotine ratio than their usual brand (which is often the case with lower delivery products), the smokers will in fact increase the amounts of tar and gas phase that they take in, in order to take the same amount of nicotine."<sup>15</sup>

#### E. Free-Basing Nicotine and the Importance of Speed in Developing and Sustaining Nicotine Addiction

For over three decades the industry worked to alter the chemical form of nicotine to increase the percentage of free base nicotine delivered to smokers. As a naturally occurring base, nicotine favors the salt form at low pH levels ("pHs") and the free base form at higher pHs. Free base nicotine transits biological membranes with considerably less resistance than does the "bound" form.

<sup>13</sup> The Nowland Organization, Inc., Management Report: SHF Cigarette Marketplace Opportunities Search and Situation Analysis, Volume II (December 1976). Trial Exhibit #17994.

<sup>14</sup> D.E. Creighton, Compensation for Changed Delivery (June 27, 1978). Trial Exhibit #11089.

<sup>15</sup> *Id.*

The industry was well aware of these properties. A 1966 British American Tobacco report noted: "It would appear that the increased smoker response is associated with nicotine reaching the brain more quickly. . . . On this basis, it appears reasonable to assume that the increased response of a smoker to the smoke with a higher amount of extractable nicotine (*not synonymous with but similar to free base nicotine*) may be either because this nicotine reaches the brain in a different chemical form or because it reaches the brain more quickly."<sup>16</sup> The report goes on to say that for both tobacco and smoke, the higher the pH, the greater the percentage of extractable nicotine. A 1971 Liggett memo stated, "Increasing the pH of a medium in which nicotine is delivered increases the physiological effect of the nicotine by increasing the ratio of free base to acid salt form, the free base form being more readily transported across physiological membranes. We are pursuing this project with the eventual goal of lowering the total nicotine present in smoke while increasing the physiological effect of the nicotine which is present, so that no physiological effect is lost on nicotine reduction."<sup>17</sup>

Industry scientists were well aware of the effect of pH on the speed of absorption and the physiologic response. A 1973 R.J. Reynolds ("RJR") report stated, "Since the unbound nicotine is very much more active physiologically, and much faster acting than the bound nicotine, the smoke at a high pH seems to be strong in nicotine. Therefore, the amount of free nicotine in the smoke may be used for at least a partial measure of the physiological strength of the cigarette."<sup>18</sup>

By the early 1970's it was recognized throughout the industry that pH alterations could serve as a means to change the

<sup>16</sup> J.D. Blackhurst, *Further Work on 'Extractable' Nicotine*. Report issued by I.W. Hughes (September 30, 1966). Trial Exhibit #17825.

<sup>17</sup> R.K. Williams, *Development Of A Cigarette With Increased Smoke pH* (December 16, 1971). Trial Exhibit #11903.

<sup>18</sup> J.D. Woods, G.C. Harllee, *Historical Review of Smoke pH Data and Sales Trends for Competitive Brand Filter Cigarettes* (May 10, 1973). Trial Exhibit #12337.



form of nicotine to a more physiologically active configuration. In a 1973 RJR memo, Frank Colby said, "Still, with an old style filter, any desired additional nicotine 'kick' could be easily obtained through pH regulation."<sup>19</sup> In another RJR memo from 1976, McKenzie said, "The pH also relates to the immediacy of the nicotine impact. As the pH increases, the nicotine changes its chemical form so that it is more rapidly absorbed by the body and more quickly gives a 'kick' to the smoker."<sup>20</sup> A 1973 RJR document stated, "Methods which may be used to increase smoke pH and/or nicotine 'kick' include: (1) increasing the amount of (strong) burley in the blend, (2) reduction of casing sugar used on the burley and/or blend, and (3) use of alkaline additives, usually ammonia compounds, to the blend."<sup>21</sup>

By the mid 1980's all the major cigarette manufacturers were engaged in pH manipulation of cigarette smoke, and this was seen as a way to compete in the marketplace. In a 1989 B&W document, Johnson said, "AT (*ammonia technology*) is the key to competing in smoke quality with PM (*Philip Morris*) worldwide. All U.S. manufacturers except Liggett use some form of AT on some cigarette products."<sup>22</sup> Philip Morris commenced use of ammonia in their Marlboro brand in the mid 1960s, and it subsequently emerged as the leading national

<sup>19</sup> Memorandum from F.G. Colby to R.A. Blevins, Jr., *Cigarette Concept to Assure RJR a Larger Segment of the Youth Market* (December 4, 1973). Trial Exhibit #12464.

<sup>20</sup> Memorandum from J.L. McKenzie to A.P. Ritchy, *Product Characterization Definitions And Implications* (September 21, 1976). Trial Exhibit #12270.

<sup>21</sup> C.E. Teague, *Implications and Activities Arising From Correlation of Smoke pH with Nicotine Impact, Other Smoke Qualities, and Cigarette Sales* (1973). Trial Exhibit #13155.

<sup>22</sup> R.R. Johnson, *Ammonia Technology Conference Minutes*, Louisville, KY, May 18-19, 1989 (June 12, 1989). Trial Exhibit #13069.

brand. Reverse engineering by Philip Morris' competitors eventually led each one to the conclusion that ammoniation in some form was "the secret of Marlboro".<sup>23</sup>

Perhaps the most insidious aspect of ammonia technology was the recognition in the industry that the FTC testing method for determining tar and nicotine in smoke could be made meaningless. Not only does the testing method fail to accurately reflect a smoker's tar and nicotine intake, the method only measures the nicotine in the particulate or aerosol phase and is incapable of assessing the "form," i.e. bound or free base, in which nicotine exists. Further understanding of this was evident in another B&W document from 1984: "The amount of nicotine in the vapor phase can be modified by changing the acidity (pH) of the smoke. Hence it is readily feasible to have two cigarettes which deliver the same amount of nicotine (as measured on a Cambridge pad—the *FTC method*) but which are easily differentiated on the sensory basis of impact since the acidity of the smoke (and hence amount of nicotine in the vapor phase) is different."<sup>24</sup> Woods from RJR also was aware of this concept as early as 1973. "The FTC 'tar' and nicotine has decreased for all brands studied at about the same rate. Thus, all the brands have about the same FTC 'tar' and nicotine, but the Marlboro and Kool are stronger due to a higher smoke pH."<sup>25</sup> A 1973 RJR document explained, "All evidence indicates that the relatively high smoke pH (high alkalinity) shown by Marlboro (and other Philip Morris brands) and Kool is deliberate and controlled."<sup>26</sup> Graphs in this document plotted sales vs. pH vs. free base nicotine for Winston and Marlboro;

<sup>23</sup> See Johnson, *Ammonia Technology Conference Minutes* (June 12, 1989).

<sup>24</sup> Memorandum to Dr. L.C.F. Blackman and Mr. A.M. Heath, *Proceedings Of The Smoking Behavior-Marketing Conference*, July 9-12, 1984, session I (July 30, 1984). Trial Exhibit #13430.

<sup>25</sup> See Woods, *Historical Review of Smoke pH Data and Sales Trends for Competitive Brand Filter Cigarettes* (May 10, 1973).

<sup>26</sup> See Teague, *Implications and Activities Arising from Correlation of Smoke pH With Nicotine Impact, Other Smoke Qualities, and Cigarette Sales* (1973).

the graphs show that Marlboro sales increased as the pH and percent free base nicotine increased for the years 1955 through the early 1970's. Additional evidence of the industry's investigation into pH manipulation comes from a 1994 Philip Morris document, "To illustrate, a study was conducted on nicotine aerosols, where subjects inhaled the same amount of nicotine at pHs of 5.6, 7.5 and 11.0. It was found that higher peak concentrations of nicotine in blood were achieved at higher pHs. Since the amounts of inhaled nicotine were the same, the results indicate that the higher the pH, the more rapidly nicotine enters the bloodstream."<sup>27</sup>

Ammonia compounds are among the most abundant additives used in the manufacture of cigarettes in this country. The industry contends that ammonia compounds are added for taste, not to "free base" the nicotine. However, neither the science nor internal industry documents support that contention.

#### F. Cigarettes: A Product of a Tobacco or Drug Industry?

That nicotine is a drug, the cigarette a delivery device and tobacco companies are in the drug business, has not escaped the focus of the industry. Claude E. Teague, Jr., Assistant Director of Research at RJR could have been speaking for the entire industry in a 1972 memorandum: "In a sense, the tobacco industry may be thought of as being a specialized, highly ritualized and stylized segment of the pharmaceutical industry. Tobacco products, uniquely, contain and deliver nicotine, a potent drug with a variety of physiological effects. . . . Thus a tobacco product is, in essence, a vehicle for delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form. Our Industry is then based upon design, manufacture and sale of attractive dosage forms of nicotine, and our Company's position in our Industry is determined by our ability to produce dosage forms of nicotine which have more overall value, tangible or intangible, to the consumer than those of our

<sup>27</sup> *The Effects of Cigarette Smoke "pH" on Nicotine Delivery and Subjective Evaluations* (June 24, 1994). Trial Exhibit #11752.

competitors. . . . If nicotine is the sine qua non of tobacco products and tobacco products are recognized as being attractive dosage forms of nicotine, then it is logical to design our products—and where possible, our advertising—around nicotine delivery rather than "tar" delivery or flavor. . . . If, as proposed above, nicotine is the sine qua non of smoking, and if we meekly accept the allegations of our critics and move toward reduction or elimination of nicotine from our products, then we shall eventually liquidate our business. If we intend to remain in business and our business is the manufacture and sale of dosage forms of nicotine, then at some point we must make a stand."<sup>28</sup>

Publicly admitting that nicotine is a drug had potential regulatory implications. In a 1969 Philip Morris document, Dunn wrote to H. Wakeham, Director of R&D, "I would be more cautious in using the pharmacomedical model—do we really want to tout cigarette smoke as a drug? It is, of course, but there are dangerous FDA implications to having such conceptualization go beyond these walls."<sup>29</sup> Dunn expressed similar concerns in a 1980 letter to R. B. Seligman: "Any action on our part, such as research on the psychopharmacology of nicotine, which implicitly or explicitly treats nicotine as a drug, could well be viewed as a tacit acknowledgment that nicotine is a drug. Such acknowledgment, contend our attorneys, would be untimely."<sup>30</sup> A. D. McCormick at British American Tobacco in 1974 was also concerned about the FDA: "If tobacco were to be placed under a Food and Drug law, classification of tobacco under the food section would be acceptable, but classification of

<sup>28</sup> Memorandum from C.E. Teague, Jr., *The Nature of the Tobacco Business and the Crucial Role of Nicotine Therein* (April 14, 1972). Trial Exhibit #12408.

<sup>29</sup> Memorandum from W.L. Dunn, Jr. to Dr. H. Wakeham, *Jet's Money Offer* (February 19, 1969). Trial Exhibit 10539.

<sup>30</sup> Memorandum from W.L. Dunn to R.B. Seligman, *The Nicotine Receptor Program* (March 21, 1980). Trial Exhibit #26227.



tobacco as a drug should be avoided at all costs."<sup>31</sup> In a 1980 memo to R. B. Seligman and Directors of Philip Morris, Thomas Osden outlined the priorities for "Evaluation of Major R&D Programs".<sup>32</sup> About the nicotine program, he stated, "This program includes both behavioral effects as well as chemical investigation. My reason for this high priority is that I believe the thing we sell most is nicotine."<sup>33</sup>

The concept of the cigarette as a drug delivery device is deeply rooted in the industry. W. L. Dunn, in a 1972 Philip Morris document, summarized the discussion at a conference attended by 25 scientists from England, Canada and the United States: "The majority of conferees would accept the proposition that nicotine is the active constituent of cigarette smoke. . . . The cigarette should be conceived not as a product but as a package. The product is nicotine."<sup>34</sup>

Researchers at British American Tobacco wrote, "BAT should learn to look at itself as a drug company rather than as a tobacco company."<sup>35</sup> Finally, Addison Yeaman, General Counsel of B&W, said more than three decades ago, "We are, then in the business of selling nicotine, an addictive drug."<sup>36</sup>

**G. Marketing to Children—Is "addiction" really free choice?**

The tobacco industry argues that the decision to smoke and to continue smoking is a free choice made by adults. The main problem with this defense is that nicotine addiction is a

<sup>31</sup> Memorandum from A.D. McCormick, *Smoking and Health* (May 3, 1974). Trial Exhibit #10602.

<sup>32</sup> Letter from T.S. Osden to R.B. Seligman, *Evaluation of Major R&D Programs* (August 12, 1980). Trial Exhibit #10255.

<sup>33</sup> *Id.*

<sup>34</sup> See Dunn, *Motives and Incentives in Cigarette Smoking*.

<sup>35</sup> R.A. Crellin, *Brainstorming II: What Three Radical Changes Might, Through the Agency of R&D, Take Place in this Industry by the End of the Century?* (April 11, 1980). Trial Exhibit #11361.

<sup>36</sup> P. Hilts, *Tobacco Company Was Silent on Hazards*, New York Times, 1994, at 1.

condition that begins for most in childhood.<sup>37</sup> Furthermore, the "choice" argument is impossible to defend in the face of nicotine addiction because children may "choose" to experiment with cigarettes, but they do not choose to become addicted. The reason for the tobacco industry's public denial of nicotine addiction was clearly stated in a 1980 Tobacco Institute document which said: "Shook, Hardy (Shook, Hardy and Bacon, L.L.P., is a Kansas City law firm that has directed legal strategy for the tobacco industry<sup>38</sup>) reminds us, I'm told, that the entire matter of addiction is the most potent weapon a prosecuting attorney can have in a lung cancer/cigarette case. We can't defend continued smoking as 'free choice' if the person was 'addicted'. "<sup>39</sup>

Most adult smokers start smoking before the age of 18, a fact that has been well known by the tobacco industry and its marketing departments for decades. For example, in a report to the Board of Directors of RJR on September 30, 1974, entitled, "1975 Marketing Plans Presentation, Hilton Head, September 30, 1974," one of the key opportunities to accomplish the goal of re-establishing RJR's market share was proclaimed to be: "[I]ncrease our young adult franchise. . . . First, let's look at the growing importance of this young adult in the cigarette market. In 1960, this young adult market, the 14-24 age group,

<sup>37</sup> D. Kessler, *Nicotine Addiction in Young People*, 333 New Eng. J. Med., 186-189 (1995).

<sup>38</sup> S.A. Glantz, D.E. Barnes, L. Bero, P. Hanauer, J. Slade, *Looking Through a Keyhole at the Tobacco Industry: The Brown and Williamson documents*, 274 JAMA 219-224 (1995); P. Hanauer, J. Slade, D.E. Barnes, L. Bero, S.A. Glantz, *Lawyer Control of Internal Scientific Research to Protect Against Products Liability Lawsuits: The Brown and Williamson documents*, 274 JAMA 234-240 (1995); L. Bero, D.E. Barnes, P. Hanauer, J. Slade, S.A. Glantz, *Lawyer Control of the Tobacco Industry's External Research Program: The Brown and Williamson documents*, 274 JAMA 241-247 (1995).

<sup>39</sup> Memorandum from P.C. Knopick to W. Kloepper (September 9, 1980). Trial Exhibit #14303.

represented 21 percent of the population. . . . They will represent 27% of the population in 1975. They represent tomorrow's cigarette business."<sup>40</sup>

The first strategy listed was: "1—Direct advertising appeal to the younger smokers . . .".<sup>41</sup> These marketing plans became the marketing goals under RJR's 1975 domestic operating goals.<sup>42</sup>

In a 1980 RJR document entitled, "MDD Report on Teenage Smokers (14-17)", a future CEO, G. H. Long, wrote to the CEO at that time, E. A. Horrigan, Jr. In this document, Long is lamenting the loss of market share of the 14- to 17-year-old smokers to Marlboro. "Hopefully, our various planned activities that will be implemented this fall will aid in some way in reducing or correcting these trends."<sup>43</sup>

That the industry focused a lot of attention on children was evident in other documents such as a survey performed for Philip Morris in 1974<sup>44</sup> in which children age 14 or younger were being interviewed about their smoking behavior<sup>45</sup> and in a 1979 Philip Morris document which said amongst other things, "Marlboro dominates in the 17 and younger category, capturing over 50 percent of this market."<sup>46</sup> When 30% of 3 year olds and nearly 90% of 5 year olds associate a picture of "Joe Camel" with cigarettes<sup>47</sup>, it is obvious that these directed marketing efforts are extremely influential.

<sup>40</sup> C.A. Dukes, 1975 Marketing Plans Presentation to RJRI Board of Directors (September 30, 1974). Trial Exhibit #12493.

<sup>41</sup> *Id.*

<sup>42</sup> *Domestic Operating Goals* (November 26, 1974). Trial Exhibit #12377.

<sup>43</sup> Memorandum from G.H. Long to E.A. Horrigan, Jr., *MDD Report on Teenage Smokers* (14-17) (July 22, 1980). Trial Exhibit #13101.

<sup>44</sup> The Roper Organization Inc., *A Study of Smoking Habits Among Young Smokers* (July 1974). Trial Exhibit #10497.

<sup>45</sup> G. Bible, Minnesota Tobacco Trial Transcript at 6097 (March 8, 1998).

<sup>46</sup> Marlboro (March 29, 1979). Trial Exhibit #11808.

<sup>47</sup> MacKensie et al., *New Eng. J. Med.*, April 7, 1994, at 975-80.

#### H. How Nicotine Addiction Affects Our Nation's Youth

Three thousand children start smoking every day.<sup>48</sup> Of these 3000, in their lifetime, 23 will be murdered, 30 will die in an automobile accident and more than 1000 will die prematurely from smoking related diseases. Approximately two-thirds of people who smoke begin by age 14 and over 90% do so by age 19. The number of college students who have smoked in the last 30 days rose by nearly 28% from 1993 to 1997. In some states the rate of smoking among high school students has risen by 70%.

These statistics are overwhelming especially in light of the health hazards associated with tobacco smoking by children. Children that begin smoking at age 15 have twice the incidence of lung cancer as do those who start at age 25.<sup>49</sup> Of additional concern are more recent findings of the adverse effects noted very early on in young smokers. Their heart rates are 2 to 3 beats per minute faster than nonsmokers.<sup>50</sup> Changes of the arterial inner wall that will lead to hardening of the arteries are evident.<sup>51</sup> A study of 10- to 18-year-old smokers found statistical evidence of airway function impairment (possibly early emphysema) and slowed growth of lung function.<sup>52</sup> Genetic mutations can be found in newborns of smoking mothers that predispose their children to blood malignancies in childhood.<sup>53</sup> Smoking mothers have higher spontaneous abortion rates and lower birth weight babies. These babies suffer from respiratory distress, pneumonia and higher neonatal death rates. Maternal smoking has been shown to cause a "catastrophic disruption" of the chromosomes in human eggs that can lead to miscarriages

<sup>48</sup> 1994 Surgeon General's Report, *Preventing Tobacco Use Among Young People*.

<sup>49</sup> *Cigarette Smoking and Health*, *Am. J. Respir. Crit. Care Med.*, Vol. 153 at 861-5 (1996).

<sup>50</sup> See 1994 Surgeon General's Report, at 28.

<sup>51</sup> Celemajer et al., *New Eng. J. Med.*, January 18, 1996, at 150-4.

<sup>52</sup> Gold et al., *New Eng. J. Med.*, September 26, 1996, at 931-7.

<sup>53</sup> Finette et al., *Nature Medicine*, October 1998, at 1144-51.



as well as cause chromosome changes associated with lymphoma. Another study found that benzopyrene produces genetic changes typical of those seen in human lung cancer.<sup>54</sup> The earlier one begins to smoke, the greater these changes. And if this is not enough, it should not be overlooked that nicotine is an introductory drug ("gateway drug"), as smokers are 15 times more likely to become an alcoholic, to become addicted to "hard drugs" or to develop a problem with gambling.

### CONCLUSION

Nicotine is a powerful, addictive drug. We, the treating physicians, know it. The industry, despite its many attempts to deny or dilute the truth, knows it. But do our children know it? And if they know it, does it mean that they truly understand the consequences of nicotine addiction? The answer to this question is no. No sane person would consciously choose the inevitable diseases and resulting death associated with tobacco use. Like all other drugs, it is essential that the FDA have the legal authority to regulate the sale and promotion of tobacco products. Children are the least likely population to exercise "free choice". The younger these kids start smoking, the more powerful the addiction is to nicotine. The stronger the addiction, the harder it is to stop. The longer they smoke, the shorter they live. For these reasons, we respectfully request this Court to reverse the Fourth Circuit's ruling and find that the FDA has the legal authority to regulate tobacco usage among minors.

<sup>54</sup> Denissenko et. al., Science, October 18, 1996, at 430-2.

Respectfully submitted,

Raymond D. Cotton\*  
Aliza A. Danoff  
Mintz Levin Cohn Ferris Glovsky &  
Popeo, P.C.  
701 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004  
(202) 434-7300

*Attorneys for American College  
of Chest Physicians*

\* Counsel of Record

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**Appendix A****PLEDGE**

*As a Fellow of American College of Chest Physicians and a leader in the most important struggle faced by chest physicians, the prevention and control of our major health problems of lung cancer, cardiovascular and chronic pulmonary disease, I shall make a special personal effort to control smoking and to eliminate this hazard from my office, clinic, and hospital. I shall ask all of my patients about their smoking habits, and I shall assist the cigarette smoker in stopping smoking. I make this pledge to my patients and to society.*